

Claims

1. A method for analyzing an anticoagulated whole blood sample for the presence or absence of target circulating blood cells which are characterized by target cell membrane epitopes which epitopes are expressed as the result of a particular biological cellular condition in the target cells, said method comprising the steps of:
 - a) providing a transparent container having a cavity containing an insert, said container and insert combining to form a free volume between the insert and a wall or walls of the container;
 - b) combining the blood sample with one or more target epitope-specific labeling agents so as to colorimetrically differentiate any individual target cells in the blood sample from other cells in the blood sample;
 - c) placing the blood sample in the container and centrifuging the blood sample in the container so as to cause any individual target cells present in the blood sample to localize in said free volume in the container;
 - d) examining the centrifuged blood sample for the presence or absence of any individual differentiated target cells found *in situ* in the free volume in the container; and
 - e) said combining step being performed either before or after the blood sample is placed in the container.
2. The method of Claim 1 wherein said target cells are cells which are infected by a virus that causes the expression of target epitopes and wherein the target epitopes are characterized by the infecting virus.
3. The method of Claim 2 wherein the infecting virus is HIV-1 and an expressed target

epitope is gp120.

4. The method of Claim 2 wherein the infecting virus is CMV and the expressed target epitopes are CMV-specific glycoproteins.

5. The method of Claim 2 wherein the infecting virus is CMV and the expressed target epitopes are CMV-specific antigens.

6. The method of Claim 2 wherein the infecting virus is HCV and the expressed target epitopes are epitopes which can be detected by monoclonal antibodies selected from the group consisting of: 4,6E7-F6; 1,4G11-B4G10; 2C4G3; 22A5B12; 20A6F3; and mixtures thereof.

7. The method of Claim 2 wherein the infecting virus is EBV and the expressed target epitopes are epitopes which can be detected by B532 monoclonal antibodies.

8. The method of Claim 1 wherein the infecting virus is EBV and the expressed target epitopes are epitopes which can be detected by B532 monoclonal antibodies.

9. The method of Claim 1 wherein said examining step is performed with an automated microscopal instrument.

10. The method of Claim 1 wherein said well-defined free volume has a transverse thickness which is essentially equal to a focal operating range of a microscopal instrument at a predetermined power, which instrument is used to examine the sample.

11. A method for detecting circulating target fetal blood cells in a sample of a pregnant female donor's blood, which target fetal blood cells express human leukocyte antigens (target HLA epitopes) that differ from the donor's unique HLA epitopes, said method comprising the steps of:

- a) providing a transparent container having a cavity containing an insert, said container and insert combining to form a free volume between the insert and a wall or walls of the container;
 - b) combining the blood sample with one or more target HLA epitope-specific labeling agents so as to colorimetrically differentiate any individual target cells in the blood sample from other cells in the blood sample;
 - c) placing the blood sample in the container and centrifuging the blood sample in the container so as to cause any individual target cells present in the blood sample to localize in said free volume in the container;
 - d) examining the centrifuged blood sample for the presence or absence of any individual differentiated target cells found *in situ* in the free volume in the container;
- and
- e) said combining step being performed either before or after the blood sample is placed in the container.

12. A method for detecting circulating target donor blood cells in a sample of a recipient's blood, which target donor blood cells express human leukocyte antigens (target HLA epitopes) that differ from the recipient's unique HLA epitopes, said method comprising the steps of:

- a) providing a transparent container having a cavity containing an insert, said container and insert combining to form a free volume between the insert and a wall or

walls of the container;

b) combining the blood sample with one or more target HLA epitope-specific labeling agents so as to colorimetrically differentiate any individual target donor blood cells in the blood sample from recipient blood cells in the blood sample;

c) placing the blood sample in the container and centrifuging the blood sample in the container so as to cause any individual target cells present in the blood sample to localize in said free volume in the container;

d) examining the centrifuged blood sample for the presence or absence of any individual differentiated target cells found *in situ* in the free volume in the container; and

e) said combining step being performed either before or after the blood sample is placed in the container.

13. A method for detecting circulating target leukocyte blood cells in a sample of a transplant or graft recipient's blood, which target leukocyte blood cells express human leukocyte antigens (target HLA epitopes) that differ from the recipient's unique HLA epitopes, said method comprising the steps of:

a) providing a transparent container having a cavity containing an insert, said container and insert combining to form a free volume between the insert and a wall or walls of the container;

b) combining the blood sample with one or more target HLA epitope-specific labeling agents so as to colorimetrically differentiate any individual target leukocyte cells in the blood sample from other leukocyte cells in the blood sample;

c) placing the blood sample in the container and centrifuging the blood sample in the container so as to cause any individual target leukocyte cells present in the blood sample to localize in said free volume in the container;

- d) examining the centrifuged blood sample for the presence or absence of any individual differentiated target leukocyte cells found *in situ* in the free volume in the container; and
- e) said combining step being performed either before or after the blood sample is placed in the container.

14. A method for analyzing an anticoagulated whole blood sample for the presence or absence of target circulating blood cells which are characterized by target cell membrane epitopes which epitopes are expressed as the result of a particular biological cellular condition in the target cells, said method comprising the steps of:

- a) providing a transparent container having a cavity containing an insert, said container and insert combining to form a free volume between the insert and a wall or walls of the container;
- b) combining the blood sample with one or more target epitope-specific labeling agents so as to colorimetrically differentiate any individual target cells in the blood sample from other cells in the blood sample;
- c) placing the blood sample in the container and centrifuging the blood sample in the container so as to cause any individual target cells present in the blood sample to localize in said free volume in the container;
- d) examining the centrifuged blood sample for the presence or absence of any individual differentiated target cells found *in situ* in the free volume in the container and enumerating any differentiated target cells which are noted in the sample; and
- e) said combining step being performed either before or after the blood sample is placed in the container.

15. The method of Claim 14 wherein said examining and enumerating steps are

performed with an automated microscopical instrument.

16. The method of Claim 14 wherein said target cells are cells which are infected by a virus that causes the expression of target epitopes and wherein the target epitopes are characterized by the infecting virus.

2007-01-01